

ABSTRACT

The present invention relates to the inclusion complexes of butylphthalide, which is D, L-mixed or levorotatory, with cyclodextrin or cyclodextrin derivatives, to a process for their preparation and the use thereof. In the invention, the butylphthalide is complexed with cyclodextrin or cyclodextrin derivatives, preferably with hydroxypropyl- β -cyclodextrin, in order to increase the water-solubility of butylphthalide, develop clinical solid or liquid formulations and improve the therapeutic effect of butylphthalide. The inclusion complex, in which the molar ratio of butylphthalide to cyclodextrin or cyclodextrin derivatives is in the range of 1:1-10, can be used to prepare infusion, injection, injectable powder, liquids for oral administration, syrup, tablets, granules, dispersible tablets and others.